

Application No. 10/081,118

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Docket No.: 22321-00002-US1

REMARKS

Claims 3-6, 9-11, and 19-25 are pending in the application and stand rejected.
Independent claims 19 and 20, and dependent claim 23, are amended.

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Rejections under 35 USC 112.

Claims 22-25 stand rejected as reciting new subject matter.

As a first matter, the specification recites that the disclosed reagent comprises "at least one detergent." P. 6, ll. 1-2. The term is understood broadly to permit a combination of detergents. Saponins are specifically recited as suitable detergents on p. 7, l. 21. One of skill in the art would recognize that saponins are in the class of non-ionic detergents. Other non-ionic detergents suitable in the invention are disclosed on page 7. Thus the specification provides adequate support for claim 22. An exact and literal recitation of the words of the claim is not necessary or required.

Support for claims 23-25 is found on page 9, l. 31 to p. 10, l. 4. Moreover, claim 23 has been amended to depend directly from claim 20.

Rejections under 35 USC 103.

Claims 3-6, 9-11, and 19-21 stand rejected as obvious over Sakata (US5496734) in view of Haas et al. (Methods in Enzymol. 173:280 (1989)), and optionally in view of FR 97 01090.

With regard to Sakata et al., there appear to be at least two main differences between the Sakata et al. reference and the present invention. One, Sakata et al. does not disclose the use of an ionophore, as acknowledged by the Examiner. Two, Sakata et al. disclosed a "pretreatment method." Col. 2, l. 62. By contrast, the present claims as amended provide for *simultaneous* lysis of erythrocytes, fixing of nucleate cells, and staining of intracellular material. Page 5, ll. 16-20. The Haas et al. reference does certainly not supply both of the missing elements. Similarly, the description of Veriac et al. in the background does not address both elements.

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For at least these reasons, the claims as amended should be allowed.

Moreover, the Examiner also states that Sakata et al. discloses a reagent that lyses erythrocytes. Page 4. According to our understanding, Sakata et al. is at best ambiguous with regard to the effect on erythrocytes. For example, Sakata et al. state: "leukocytes can be selectively classified and counted by treating the whole blood sample without removing erythrocyte and blood platelet cells." Col. 6, ll. 59-63. In another place, Sakata et al. state: "The nonionic surfactant also will act to accelerate the lysis of erythrocytes, which causes a problem in the case of measuring leukocytes contained in a blood sample." Col. 9, ll. 58-61. The foregoing texts suggest that the aim of Sakata et al. is to NOT lyse erythrocytes.

Furthermore, the Examiner states that Sakata et al. discloses a reagent for identifying, counting, and classifying blood cells. This is an overgeneralization, because Sakata states: "According to the method of the present invention, only leukocytes can be selectively labeled ... by using an untreated blood sample." Col. 3, ll. 9-11. By contrast, the composition of the present invention also labels reticulocytes.

The reference by Haas et al. is directed to use of ionophores with red blood cells and cells in tissue culture. Haas et al. provides no insight into use of ionophores with leukocytes or reticulocytes. In contrast, the claimed invention does not seek to stain red blood cells (or tissue culture cells) because mature human red blood cells have no nuclei. Thus, one of skill in the art could find no motivation in Haas et al. to combine the references.

The Applicant has advised that Veriac does not describe the elements absent in Sakata to obtain the instant invention. Sakata fails to teach the simultaneous lysis, fixation and staining of the cell as made by the reagent of the invention. Moreover, Sakata does teach coloration of nucleated cells. Veriac does not teach coloration of nucleated cells.

Thus, even by combining the teaching of the references, one of skill in the art would not obtain the invention as claimed.

In view of the above arguments and amendments, applicant believes the pending application is in condition for allowance.

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A Request for Continued Examination and request for a two-month extension of time accompany this response. Please charge our Deposit Account No. 22-0185, under Order No. 22321-00002-US1 from which the undersigned is authorized to draw for the fee for the Request for Continued Examination and the two-month extension of time. If other fees are required to maintain pendency of the application, the Commissioner is authorized to charge Deposit Account No. 22-0185 for those fees, or to credit the account for any overcharges.

If direct communication would speed the prosecution of the application to issue, please call me.

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Respectfully submitted,

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